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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,661	09/23/2003	Jean-Claude Yvin	16721-0250 (42528-292745)	1057
881	7590	02/16/2006	EXAMINER	
STITES & HARBISON PLLC 1199 NORTH FAIRFAX STREET SUITE 900 ALEXANDRIA, VA 22314			HENRY, MICHAEL C	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 02/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/668,661

Applicant(s)

YVIN ET AL.

Examiner

Michael C. Henry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>06/24/05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-10 are pending in application

Information Disclosure Statement

The information disclosure statement filed complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 2 recite the phrase “comprising administration”. However, the phrase renders the claims indefinite, since it is unclear to whom or what the compound is being administered. More specifically, it is unclear who the recipient is intended to be. Furthermore, claims 1 and 2 are indefinite for failing to particularly point out what disease(s) or condition(s) is being treated by the administration of said agents or compounds or for what purpose are the agents administered. Consequently, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claims 3 and 4 recite the phrases “naturally derived compounds and “miscellaneous drugs”. However, these phrases render the claims indefinite, since it is unclear which compounds are considered naturally derived compounds and how or from what the said

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compounds must be derived in order to be considered a naturally derived compound. Also, it is unclear what drugs or compounds are considered miscellaneous drugs.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 5, 7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Di Luzio et al. (Progress in Cancer Research and Therapy (1978), 7 (Immune Modulation Control Neoplasia Adjuvant Ther.), 171-82).

In claim 1, applicant claims “Chemotherapeutic antineoplastic method comprising administration of an effective amount of an antineoplastic agent in conjunction with an effective amount of a β -1,3 glucan. Di Luzio et al. disclose applicant’s method comprising the administration of an effective amount of an antineoplastic agent (cyclophosphamide) in conjunction (combination) with an effective amount of a β -1,3 glucan (CAS # 9012-72-0) to rats (see abstract). Claim 3 is drawn to a method according to claim 1 wherein the antineoplastic agent is selected from specific compound including alkylating agents. Di Luzio et al. disclose applicant’s method wherein the antineoplastic agent is alkylating agent, cyclophosphamide (see abstract). Claim 5 is drawn to a method according to claim 1 wherein the antineoplastic agent is cyclophosphamide. Di Luzio et al. disclose applicant’s method wherein the antineoplastic agent is cyclophosphamide (see abstract). Claim 7 is drawn to a chemotherapeutic antineoplastic method according to claim 1 wherein the β -1,3 glucan is administered orally, intravenously or

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intraperitoneally. Di Luzio et al. disclose applicant's method wherein the β -1,3 glucan is administered intravenously (see abstract). Claim 9 is drawn to a chemotherapeutic antineoplastic method according to claim 1 wherein the β -1,3 glucan is administered before, simultaneously to or after the antineoplastic agent. Di Luzio et al. disclose applicant's method wherein the β -1,3 glucan is administered simultaneously to (in combination with) the antineoplastic agent (see abstract).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 4, 6, 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Di Luzio et al. in view of Yvin et al. (US 2003/0119780 A1).

In claim 2, applicants claim a "Chemotherapeutic antineoplastic method comprising administration of an effective amount of an antineoplastic agent in conjunction with an effective amount of laminarin. Claims 2, 4, 6, 8 and 10 are drawn said method according to claim 2 involving the use of specific antineoplastic agents, the use of the antineoplastic agent, cyclophosphamide, and specific routes and ways of administration of the laminarin and the antineoplastic agent.

Di Luzio et al. disclose a method comprising the administration of an effective amount of an the antineoplastic agent, cyclophosphamide for the treatment tumors in rats (see abstract).

Furthermore, Di Luzio et al. disclose a method comprising the administration of an effective

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amount of an antineoplastic agent (cyclophosphamide) in conjunction (combination) with an effective amount of a β -1,3 glucan (CAS # 9012-72-0) to rats (see abstract).

The difference between applicant's claimed method and Di Luzio et al.'s method is that Di Luzio et al. do not use the glucan, laminarin.

Yvin et al. disclose a method treating cancer growth (tumor growth) comprising the administration of an effective amount of soluble laminarin to mice (see page 4, sections [0094] to [0099]).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Di Luzio et al and Yvin et al., to have used the method of Di Luzio et al. to prepare a composition comprising a combination of a antineoplastic agent such as cyclophosphamide and a glucan such as laminarin to treat tumors, since the combination of compounds that are used to treat the same diseases or conditions are well known in the art. More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

One having ordinary skill in the art would have been motivated in view of Di Luzio et al and Yvin et al., to have used the method of Di Luzio et al. to prepare a composition comprising a combination of a antineoplastic agent such as cyclophosphamide and a glucan such as laminarin to treat tumors, because a skilled artisan would reasonably be expected to prepare a composition comprising a combination of the compounds taught by Di Luzio et al and Yvin et al., to treat tumors based on type, stage and/or severity of the tumors.

Conclusion

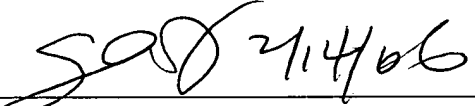
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652.

The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang, Ph.D can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

Michael C. Henry



Shaojia Anna Jiang, Ph.D.
Supervisory Patent Examiner
Art Unit 1623

February 8, 2006.